

# PATENT COOPERATION TREATY

RECEIVED

From the INTERNATIONAL SEARCHING AUTHORITY

JAN 13 AM 10:35

**PCT**

To:

WOOD, HERRON & EVANS, L.L.P.  
Attn. Josephic, David J.  
2700 Carew Tower  
Cincinnati, Ohio 45202  
UNITED STATES OF AMERICA

WOOD, HERRON & EVANS

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

FOREIGN DEPT. **LALC**  
DATE **3-13-06**

(PCT Rule 44.1)

Applicant's or agent's file reference

PMAN - 24WO

**FOR FURTHER ACTION**

See paragraphs 1 and 4 below

International application No.

PCT/US2004/029360

International filing date

(day/month/year)

09/09/2004

Applicant

MINU, L.L.C.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

**For more detailed instructions,** see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.  
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

**4. Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Jaap Hurenkamp

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

#### What documents must/may accompany the amendments?

##### **Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

**The following examples illustrate the manner in which amendments must be explained in the accompanying letter:**

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### **Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

### **Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  PMAN - 24WO	<b>FOR FURTHER ACTION</b>  see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No.  PCT/US2004/029360	International filing date ( <i>day/month/year</i> )  09/09/2004	(Earliest) Priority Date ( <i>day/month/year</i> )  18/09/2003
Applicant  MINU, L.L.C.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/029360

## A. CLASSIFICATION OF SUBJECT MATTER

A61K9/10

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, MEDLINE, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 817 630 A (HOFMANN ET AL) 6 October 1998 (1998-10-06)  column 3 - column 4; example 1 claims 1-23 -----	1,3,9, 11-14, 18,19, 21-27, 31-39, 46-64
X	US 4 620 979 A (SCHACHAR ET AL) 4 November 1986 (1986-11-04)  column 2, line 38 - line 51 column 4 - column 5; examples 3,4 claims 1-8 ----- -/--	1,3,9, 11-14, 18,19, 21-27, 31-39, 46-64

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

18 November 2005

Date of mailing of the international search report

0. 03 2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Muller, S

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/029360

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 808 317 A (HECHT G,US ET AL) 30 April 1974 (1974-04-30)  column 1, line 40 - column 2, line 16 column 3, line 26 - line 63 column 3; example 1 -----	1-3,9, 11-14, 18, 21-27, 31-39, 46-51
X	US 4 711 780 A (FAHIM ET AL) 8 December 1987 (1987-12-08)  column 11 - column 12; example 10 claims 1-13 -----	1-3,9, 11-16, 18,19, 21-27, 31-39, 46-51
X	US 6 573 299 B1 (PETRUS EDWARD J) 3 June 2003 (2003-06-03)  column 2, line 23 - line 34 column 15; examples 1,2 -----	1-3,9, 13, 17-19, 21,22, 25, 30-38, 46-56
X	US 3 958 017 A (MORSE ET AL) 18 May 1976 (1976-05-18)  column 4; example 1 column 1, line 16 - line 21 column 2, line 22 - line 31 -----	1-3,9, 11-13, 15,16, 18,19, 21-25, 27-29, 31-39, 46-51
X	US 6 235 721 B1 (GHOSAL SHIBNATH) 22 May 2001 (2001-05-22)  column 1, line 9 - line 15 column 2, line 27 - line 40 column 7 - column 8; example 7a column 16; example 21 ----- -/--	1,3,9, 13,18, 21,22, 25, 31-36, 39,46,51

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/029360

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 6 146 664 A (SIDDIQUI ET AL) 14 November 2000 (2000-11-14)</p> <p>column 3, line 46 - column 4, line 7 column 5; table 1 -----</p>	<p>1,3, 9-14,18, 21-27, 31-37, 39,43, 46-51</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/029360

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5817630	A	06-10-1998	CA 2200501 A1	20-09-1998
US 4620979	A	04-11-1986	NONE	
US 3808317	A	30-04-1974	NONE	
US 4711780	A	08-12-1987	NONE	
US 6573299	B1	03-06-2003	NONE	
US 3958017	A	18-05-1976	NONE	
US 6235721	B1	22-05-2001	US 6124268 A	26-09-2000
US 6146664	A	14-11-2000	AU 4831699 A	01-02-2000
			CA 2336799 A1	20-01-2000
			EP 1096922 A1	09-05-2001
			JP 2002520267 T	09-07-2002
			WO 0002535 A1	20-01-2000



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/029360

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51  
entirely claims  
2,15-17,19,28-30,38,52-64

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent selected from at least one of cysteine, L-cystine, glutathione, L-methionine, and N-acetyl-L-cysteine.

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2. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 4,20,40

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a solution of up to 12% water and at least one water miscible organic solvent selected from the group of N-propanol, isopropanol, propylene glycol, butylene glycol, hexylene glycol, glycerine, sorbitol (polyol), di-propylene glycol, polypropylene glycol, a mixture of propylene glycol and butylene glycol with propylene glycol at 25% to 80% by weight and butylene glycol at 5% to 30% by weight.

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3. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 5,41

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises magnesium ions.

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4. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 6,42

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a combination of a phosphonic acid derivative and a metabisulfite.

---

5. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 7,44

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises acrylic or methacrylic polymers, or xanthans.

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6. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 8,45

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises an extract of the fruit of the *Emblica officinalis* plant.

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7. claims: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51,  
entirely claims 10,43

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a nonaqueous or substantially anhydrous silicone vehicle.

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# VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS

Absender: INTERNATIONALE RECHERCHENBEHÖRDE

An:

siehe Formular PCT/ISA/220

## PCT

### SCHRIFTLICHER BESCHEID DER INTERNATIONALEN RECHERCHENBEHÖRDE (Regel 43bis.1 PCT)

Absendedatum  
(Tag/Monat/Jahr) siehe Formular PCT/ISA/210 (Blatt 2)

Aktenzeichen des Anmelders oder Anwalts  
siehe Formular PCT/ISA/220

**WEITERES VORGEHEN**  
siehe Punkt 2 unten

Internationales Aktenzeichen  
PCT/US2004/029360

Internationales Anmeldedatum (Tag/Monat/Jahr)  
09.09.2004

Prioritätsdatum (Tag/Monat/Jahr)  
18.09.2003

Internationale Patentklassifikation (IPK) oder nationale Klassifikation und IPK  
A61K9/10

Anmelder  
MINU, L.L.C.

#### 1. Dieser Bescheid enthält Angaben zu folgenden Punkten:

- ☒ Feld Nr. I Grundlage des Bescheids
- ☐ Feld Nr. II Priorität
- ☐ Feld Nr. III Keine Erstellung eines Gutachtens über Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit
- ☒ Feld Nr. IV Mangelnde Einheitlichkeit der Erfindung
- ☒ Feld Nr. V Begründete Feststellung nach Regel 43bis.1(a)(i) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung
- ☐ Feld Nr. VI Bestimmte angeführte Unterlagen
- ☐ Feld Nr. VII Bestimmte Mängel der internationalen Anmeldung
- ☐ Feld Nr. VIII Bestimmte Bemerkungen zur internationalen Anmeldung

#### 2. WEITERES VORGEHEN

Wird ein Antrag auf internationale vorläufige Prüfung gestellt, so gilt dieser Bescheid als schriftlicher Bescheid der mit der internationalen vorläufigen Prüfung beauftragten Behörde ("IPEA"); dies trifft nicht zu, wenn der Anmelder eine andere Behörde als diese als IPEA wählt und die gewählte IPEA dem Internationale Büro nach Regel 66.1bis b) mitgeteilt hat, daß schriftliche Bescheide dieser Internationalen Recherchenbehörde nicht anerkannt werden.

Wenn dieser Bescheid wie oben vorgesehen als schriftlicher Bescheid der IPEA gilt, so ist der Anmelder aufgefordert, bei der IPEA vor Ablauf von 3 Monaten ab dem Tag, an dem das Formblatt PCT/ISA/220 abgesandt wurde oder vor Ablauf von 22 Monaten ab dem Prioritätsdatum, je nachdem, welche Frist später abläuft, eine schriftliche Stellungnahme und, wo dies angebracht ist, Änderungen einzureichen.

Weitere Optionen siehe Formblatt PCT/ISA/220.

#### 3. Nähere Einzelheiten siehe die Anmerkungen zu Formblatt PCT/ISA/220.

Name und Postanschrift der mit der internationalen  
Recherchenbehörde



Europäisches Patentamt - P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Bevollmächtigter Bediensteter

Muller, S

Tel. +31 70 340-2080



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**Feld Nr. I Grundlage des Bescheids**

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1. Hinsichtlich der **Sprache** ist der Bescheid auf der Grundlage der internationalen Anmeldung in der Sprache erstellt worden, in der sie eingereicht wurde, sofern unter diesem Punkt nichts anderes angegeben ist.
  - ☐ Der Bescheid ist auf der Grundlage einer Übersetzung aus der Originalsprache in die folgende Sprache erstellt worden, bei der es sich um die Sprache der Übersetzung handelt, die für die Zwecke der internationalen Recherche eingereicht worden ist (gemäß Regeln 12.3 und 23.1 b)).
2. Hinsichtlich der **Nucleotid- und/oder Aminosäuresequenz**, die in der internationalen Anmeldung offenbart wurde und für die beanspruchte Erfindung erforderlich ist, ist der Bescheid auf folgender Grundlage erstellt worden:
  - a. Art des Materials
    - ☐ Sequenzprotokoll
    - ☐ Tabelle(n) zum Sequenzprotokoll
  - b. Form des Materials
    - ☐ in schriftlicher Form
    - ☐ in computerlesbarer Form
  - c. Zeitpunkt der Einreichung
    - ☐ in der eingereichten internationalen Anmeldung enthalten
    - ☐ zusammen mit der internationalen Anmeldung in computerlesbarer Form eingereicht
    - ☐ bei der Behörde nachträglich für die Zwecke der Recherche eingereicht
3. ☐ Wurden mehr als eine Version oder Kopie eines Sequenzprotokolls und/oder einer dazugehörigen Tabelle eingereicht, so sind zusätzlich die erforderlichen Erklärungen, daß die Information in den nachgereichten oder zusätzlichen Kopien mit der Information in der Anmeldung in der eingereichten Fassung übereinstimmt bzw. nicht über sie hinausgeht, vorgelegt worden.
4. Zusätzliche Bemerkungen:

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**Feld Nr. IV Mangelnde Einheitlichkeit der Erfindung**

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1. ☐ Auf die Aufforderung zur Zahlung zusätzlicher Gebühren (Formblatt PCT/ISA/206) hat der Anmelder:
- ☐ zusätzliche Gebühren entrichtet.
  - ☐ zusätzliche Gebühren unter Widerspruch entrichtet.
  - ☐ keine zusätzlichen Gebühren entrichtet.
2. ☒ Die Behörde hat festgestellt, daß das Erfordernis der Einheitlichkeit der Erfindung nicht erfüllt ist, und hat beschlossen, den Anmelder nicht zur Zahlung zusätzlicher Gebühren aufzufordern.
3. Die Behörde ist der Meinung, daß das Erfordernis der Einheitlichkeit der Erfindung gemäß Regel 13.1, 13.2 und 13.3
- ☐ erfüllt ist.
  - ☒ aus folgenden Gründen nicht erfüllt ist:  
**siehe Beiblatt**
4. Daher ist der Bescheid für die folgenden Teile der internationalen Anmeldung erstellt worden:
- ☐ alle Teile
  - ☒ die Teile, die sich auf die Ansprüche mit folgenden Nummern beziehen: partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51 entirely claims 2,15-17,19,28-30,38,52-64

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**Feld Nr. V Begründete Feststellung nach Regel 43bis.1(a)(i) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung**

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1. Feststellung

Neuheit	Ja: Ansprüche
	Nein: Ansprüche 1,3,9,11-19,21-39,46-64
Erfinderische Tätigkeit	Ja: Ansprüche
	Nein: Ansprüche 1,3,9,11-19,21-39,46-64
Gewerbliche Anwendbarkeit	Ja: Ansprüche: 1,3,9,11-19,21-39,46-64
	Nein: Ansprüche:

2. Unterlagen und Erklärungen:

**siehe Beiblatt**

**Re Item IV.**

The different inventions are:

**Subject 1:**

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent selected from at least one of cysteine, L-cystine, glutathione, L-methionine, and N-acetyl-L-cysteine.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51 entirely claims 2,15-17,19,28-30,38,52-64)

**Subject 2:**

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a solution of up to 12% water and at least one water miscible organic solvent selected from the group of N-propanol, isopropanol, propylene glycol, butylene glycol, hexylene glycol, glycerine, sorbitol (polyol), di-propylene glycol, polypropylene glycol, a mixture of propylene glycol and butylene glycol with propylene glycol at 25% to 80% by weight and butylene glycol at 5% to 30% by weight.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 4,20,40)

**Subject 3:**

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises magnesium ions.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 5,41)

**Subject 4:**

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a combination of a phosphonic acid derivative and a metabisulfite.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 6,42)

**Subject 5:**

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises acrylic or methacrylic polymers, or xanthans.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 7,44)

Subject 6:

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises an extract of the fruit of the *Emblica officinalis* plant. (partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 8,45)

Subject 7:

A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a nonaqueous or substantially anhydrous silicone vehicle.

(partially claims 1,3,9,11-14,18,21-27,31-37,39,46-51, entirely claims 8,45)

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The problem to be solved by the present application is to provide ocular solutions containing antioxidant compositions which have been stabilized to retard their deterioration (see page 1, lines 2,3).

The proposed solutions are compositions comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent in an amount effective to stabilize the solution against oxidation (see page 2, lines 13-15).

Compositions comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent are not novel; they are known from the following prior art documents:

US5817630 discloses (see example 1 on columns 3,4 and claims 1-23) an eye drop composition comprising a) antioxidants comprising glutathione and lipoic acid, and b) vitamin E and/or vitamin C as additional antioxidants.

US4620979 discloses (see claims 1-8) an irrigation solution for use in ophthalmological surgery comprising ascorbate and glutathione.

US3808317 discloses (see column 1, lines 15-19 and example 1 on column 3) stabilised aqueous borate complexes of biologically active catechol amines for ocular delivery



including a combination of ascorbic acid and N-acetyl-L-cysteine as antioxidant system.

US4711780 discloses (see example 10 on columns 11 and 12) an eye spray comprising 5g vitamin C, 1g zinc, 100mg keratin, and 2g cysteine in 100ml water with 2% pectin and 0,05% benzalkonium chloride. The solution is used for treating conjunctival hyperemia and edema.

US6573299 discloses (see examples 1 and 2 on column 15) a topical eyelid gel or cream comprising Ascorbyl palmitate, tocopherol acetate, glutathione.

In the present application no further technical feature(s) can be distinguished that can be regarded as a "special technical feature" involved in the technical relationship among the different inventions, in the sense of Rule 13.2 PCT. Consequently, the present invention lacks unity, and the different solutions not belonging to a common inventive concept are identified as the different subjects on the communication pursuant to Art. 17(3) PCT.

The solutions presented in the present application therefore represent mere alternatives, not linked by a common inventive concept:

- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent selected from at least one of cysteine, L-cystine, glutathione, L-methionine, and N-acetyl-L-cysteine
- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a solution of up to 12% water and at least one water miscible organic solvent selected from the group of N-propanol, isopropanol, propylene glycol, butylene glycol, hexylene glycol, glycerine, sorbitol (polyol), di-propylene glycol, polypropylene glycol, a mixture of propylene glycol and butylene glycol with propylene glycol at 25% to 80% by weight and butylene glycol at 5% to 30% by weight.
- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises magnesium ions.
- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at

least one stabilizing agent which comprises a combination of a phosphonic acid derivative and a metabisulfite.

- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises acrylic or methacrylic polymers, or xanthans.
- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises an extract of the fruit of the *Emblica officinalis* plant.
- A composition comprising an ocular solution containing Vitamin C or Vitamin E and at least one stabilizing agent which comprises a nonaqueous or substantially anhydrous silicone vehicle.

**Re Item V.**

**Reasoned statement with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

### **1. Cited Documents**

The following documents are referred to in this communication:

- D1: US-A-5 817 630 (HOFMANN ET AL) 6 October 1998 (1998-10-06)
- D2: US-A-4 620 979 (SCHACHAR ET AL) 4 November 1986 (1986-11-04)
- D3: US-A-3 808 317 (HECHT G,US ET AL) 30 April 1974 (1974-04-30)
- D4: US-A-4 711 780 (FAHIM ET AL) 8 December 1987 (1987-12-08)
- D5: US-B1-6 573 299 (PETRUS EDWARD J) 3 June 2003 (2003-06-03)
- D6: US-A-3 958 017 (MORSE ET AL) 18 May 1976 (1976-05-18)
- D7: US-B1-6 235 721 (GHOSAL SHIBNATH) 22 May 2001 (2001-05-22)
- D8: US-A-6 146 664 (SIDDIQUI ET AL) 14 November 2000 (2000-11-14)

## **2. Novelty**

D1 discloses (see example 1 on columns 3,4 and claims 1-23) an eye drop composition comprising a) antioxidants comprising glutathione and lipoic acid, and b) vitamin E and/or vitamin C as additional antioxidants. The subject-matter of claims 1-3,9,11-14,18,19,21,22,31-39,46-58 is therefore not new in view of D1 (Article 33(2) PCT).

D2 discloses (see claims 1-8) an irrigation solution for use in ophthalmological surgery comprising ascorbate and glutathione. The subject-matter of claims 1-3,9,11-14,18,19,21,22,31-39,46-64 is therefore not new in view of D2 (Article 33(2) PCT).

D3 discloses (see column 1, lines 15-19 and example 1 on column 3) stabilised aqueous borate complexes of biologically active catechol amines for ocular delivery including a combination of ascorbic acid and N-acetyl-1-cysteine as antioxidant system. The subject-matter of claims 1-3,9,11-14,18,21,22,25,26,31-39,46-51 is therefore not new in view of D3 (Article 33(2) PCT).

D4 discloses (see example 10 on columns 11 and 12) an eye spray comprising 5g vitamin C, 1g zinc, 100mg keratin, and 2g cysteine in 100ml water with 2% pectin and 0,05% benzalkonium chloride. The solution is used for treating conjunctival hyperemia and edema. The subject-matter of claims 1-3,9,13,14,18,19,21,22,25,26,31-39,46-51 is therefore not new in view of D4 (Article 33(2) PCT).

D5 discloses (see examples 1 and 2 on column 15) a topical eyelid gel or cream comprising Ascorbyl palmitate, tocopherol acetate, glutathione. The subject-matter of claims 1-3,9,13,18,19,21,22,25,30-38,46-54,56-58 is therefore not new in view of D5 (Article 33(2) PCT).

D6 discloses (see column 1, lines 9-15 and example 1 on column 4) beverages comprising both vitamin C and metabolic iron which are stabilized by addition of cysteine. The subject-matter of claims 1-3,9,11-13,15,16,18,19,21-25,27-29,31-39,46-51 is therefore not new in view of D6 (Article 33(2) PCT).

D7 discloses (see example 21 on column 16) cosmetic and pharmaceutical compositions

containing a) vitamin C and b) an extract of the fruit of the *Emblica officinalis* plant as antioxidizing agent. The subject-matter of claims 1-3,9,13,14,18,19,21,22,25,26,31-39,46-51 is therefore not new in view of D7 (Article 33(2) PCT).

D8 discloses (see table 1 on column 5) stable topical compositions comprising a particulate ascorbic acid, and a silicone vehicle. The composition may include vitamin A or E. The subject-matter of claims 1-3,9-14,18,21-27,31-37,39,43,46-51 is therefore not new in view of D8 (Article 33(2) PCT).

### **3. Inventive Step**

Present claims 1,3,9,11-19,21-39,46-64 not being new over the prior art are also not inventive (Article 33(3) PCT).